MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Friday, December 14, 2001
9:01 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
BEATRICE S. BRAUN, M.D.
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ALAN R. NELSON, M.D.
JOSEPH P. NEWHOUSE, Ph.D.
JANET G. NEWPORT
CAROL RAPHAEL
ALICE ROSENBLATT
JOHN W. ROWE, M.D.
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.

Agenda item:
Assessing payment adequacy and updating Medicare payments: Physician payments, ESRD
-- Kevin Hayes, Nancy Ray

MR. HACKBARTH: Next on the agenda is assessing payment adequacy. We have two pieces in this segment. First we'll do physician payments, and then second we'll do ESRD.

DR. HAYES: Good morning. We just talked about input price indexes. The question now is, given a better input price index, what do we do about updating payments for physician services, what do we do about replacing the sustainable growth rate system? So what I'd like to do is to, first, just give you a status report on where we are with that effort to replace the SGR system. And second, to talk about controlling spending for physician services, which is one of the features of the existing system.

So just to recap where we've been with the replacement of the SGR system, recall that the system has two goals: accounting for changes in the cost of providing physician services; and second, to control spending for those services. The Commission, of course, has talked about a number of problems with this system but they tend to come back to one fundamental problem here, which is that these two goals are incompatible. It's difficult to try and update payments to make them consistent with changes in the cost of services when simultaneously trying to affect the update, move the update up or down because spending is doing something that the system doesn't allow.

So the Commission's position has been to replace the SGR system and to essentially decouple these two goals.

In effect what you've said is that using the update to get the price right for physician services is more important than trying to control spending. We'll talk in a few minutes about alternatives to the SGR system for controlling spending. You're not saying that controlling spending is unimportant, it's just that we need to decouple those two processes.

So how do we get the price right? Of course you've been discussing a way to do that which involves a two-part process: assessing payment adequacy and accounting for factors that affect costs. So the thinking in applying this to physician services the idea would be that going through that process would provide the Congress with the information needed to make a payment update decision for physician services every year.

So let's talk about what our next step will be on this effort to replace the SGR system. At the January meeting we'll ask you to agree on answers to two questions. First, are payments adequate for physician services? On that topic, recall that you addressed this issue at the November meeting, looked at data from different sources, data on things like the number of physicians billing Medicare, results of the Medicare current beneficiary survey, which includes questions about beneficiary access to care. We also have the results of MedPAC's survey of

physicians that was conducted in 1999.

So overall, if we put that information together you have some idea of whether payments were adequate in 1999. One conclusion that could be reached from that information is that payments were not too low in 1999.

What's happened since then? The most important things we know are the changes in input prices for physician services since then, and we know what the payment updates for physician services have been. In general, or on average I should say, the change in input prices has been greater than the updates.

I don't have the numbers with me, but my recollection is that the change in input prices as measured by the MEI has been in the neighborhood of 2.4 percent a year. The updates have averaged a little bit less than 1.5 percent per year when we include the two relatively large increases in payment rates that happened in 2000 and 2001, and then this most recent scheduled decrease in payment rates for 2002.

The other question that we would ask you to address at the January meeting has to do with factors that will affect costs in the coming year. In this case, given that we're putting out a report in March of 2002, the year of concern is 2003. The hope would be that we can make an update recommendation for 2003. We will have information on changes in input prices for physician services for that year, and we're also now looking to collect information on other factors that might be affecting costs that would be relevant to that discussion.

So that's more or less --

MR. HACKBARTH: I just wanted to ask for clarification on the first bullet, the payment adequacy. When we compare the actual updates with the change in input prices, how are we going to do that in view of the previous discussion? The MEI has included the productivity factor. We're talking about that potentially not being an appropriate factor for inclusion in an input price measure.

DR. HAYES: So we would take the productivity adjustment out of the MEI for purposes of that comparison. The numbers that I could cite --

MR. HACKBARTH: So the difference between the 2-point-something and 1-point-something will get much larger?

DR. HAYES: Correct.

DR. REISCHAUER: I thought you'd taken that out already. You hadn't?

DR. HAYES: No, had not. So that's what's ahead for the January meeting.

The other points I wanted to make briefly just had to do with the other goal of the SGR system, which is controlling spending. Here, as I said earlier, we're not saying that controlling spending is unimportant by separating this function from the update process. We wanted to address this issue in the March report and I need your ideas on how to proceed with that.

The first thing to keep in mind about controlling spending is that to achieve that requires control of the two components of spending, payment rates and the quantity and intensity of services.

In the case of controlling payment rates, we can contrast our current environment with what the Congress was faced with in the late 1980s when this issue of spending control was a much more important issue. Then Medicare used a different payment method, the old, customary, prevailing and reasonable payment method based on charges for services. The feeling was that that method gave physicians an incentive to raise charges, and the assumption was that that kind of a system was inflationary.

The Congress replaced that payment method in 1989 with the fee schedule that we have today. A fee schedule that includes, as a know, a set of relative weights, a conversion factor, geographic adjustments. So with a system like that it's possible, despite the recent volatility we've seen in payment rates for physician services, it is possible to control payment rates through the update process. So that's part of the spending equation.

The other part though, the quantity and intensity of services is much more difficult to control. A variety of methods, as you know, have been proposed to address this issue. The ones that we thought were most relevant to a discussion about replacing the SGR system have to do with methods for reducing fraud and abuse, and reducing either overuse or misuse of services. So I'd like to just take a second to talk about those two strategies and their possible impacts on spending relative to what we have now in the SGR system.

The way it looks, these alternative strategies would provide a weaker form of spending control than what we have in the SGR system. When we think about the SGR, first we can recognize that it is certainly a method for controlling spending. Indeed, it's designed to reduce spending for services. I say that, when we think about projections of changes in spending for physician services and contrast them with growth in the national economy, which is what drives the SGR spending target. Here we see a difference of about 0.6 percent per year. This difference assumes that CMS actuaries are right. That growth in the quantity and intensity of physician services will exceed growth in real GDP per capita.

Of course, the way the SGR system is structured, that difference will get fed back through to payment rates. It means that on average the payment update for physician services under this system will be 0.6 percentage points below whatever measure we use for the change in input prices. In this case, the way the system is set up, that's the MEI.

So we certainly have a method of controlling spending here which has considerable strength. The question the Commission has asked though is whether this is sustainable, despite the name of the system. The Commission has said that a spending target based on growth in real GDP per capita is too low. Hence, our plan here; one reason to replace the system.

The other strategies for controlling spending would be a bit weaker it appears. Focusing on a couple of methods that have been used to reduce fraud and abuse, we have coding edits, we have documentation guidelines. Rough estimates of the effects of those methods suggest that they would produce a one-time savings

of something like 1 percent of spending for physician services. Contrast that with the yearly savings that come out of the SGR system and that's where we reached the conclusion that this would be a weaker form of spending control.

The other strategy that one could consider has to do with reducing overuse and misuse of services. This is a much more difficult issue to deal with. The Agency for Healthcare Research and Quality is doing a lot of work in this area. Much work to be done. I think it's safe to view this as a long term effort, and effects of this effort would be uncertain.

So that's what we had in mind on addressing the issue of spending control in the March report. If you've got other ideas we'd love to hear them and welcome your comments on all this.

MR. HACKBARTH: Kevin, just a question about the coding edits and documentation guidelines. When we were doing the regulatory burden report this was one of the hot topics. Are we going to be inconsistent with what we said on the regulatory burden? I frankly can't remember exactly what we ended up saying on this issue there, but --

DR. HAYES: I don't remember any recommendation specific to these.

MR. HACKBARTH: Certainly there wasn't a recommendation, but in the text, as I recall, there was --

DR. HAYES: Right. I think the thing to point out here -- and this is something that we can address in the March report -- has to do with efforts to improve the documentation guidelines. That was an area of much, has been an area of much concern since the early to mid-'90s. CMS has gone through several iterations of the guidelines and efforts are now underway to further revise the guidelines. The Secretary has said that it's time for the agency, for CMS to rethink the approach here on the guidelines.

So I think there are some things to say. But I guess from a spending control standpoint the point to make here is that we have this estimate of one-time savings. But documentation guidelines of some form are already in place and there's a question of whether we can expect any further savings from this effort.

DR. NELSON: I want to express some caution about articulating these strategies as a means of controlling spending. I don't like the idea of reinforcing what I believe to be a myth in Congress. That if we stamp out fraud and abuse our worries about spending growth are going to go away. We ought to try and eliminate fraud and abuse for the proper reasons: that it's illegal and wrong. It ought to be uncoupled from our projections or our efforts to control spending.

A lot of what is being purported to be abuse is indeed just arbitrary denial of claims because they were coded improperly or because they weren't documented right. The service was delivered; it wasn't paid for, but it wasn't necessarily abuse. The physician or other provider just decided not to fight it. That goes on a lot.

The concern about overuse and misuse, what we ought to be urging is appropriate use. It may very well be that services will go up, because most of the guidelines that aren't currently

being met deal with not enough immunizations being given, not enough pap smears or mammograms or other preventive services, colorectal screening. As use is optimalized for the benefit of the beneficiary it may very well be that there will be more added services than a reduction in overuse of services.

Sooner or later somebody in Congress is going to have to point out that if we want to control spending we either have to reduce the benefits, we have to pass on more of the cost to the beneficiary, or we have to arbitrarily put a cap on it and then live with the consequences, as they did in the Maritime Provinces in Canada where in the fourth quarter of every year payments were reduced by half and all the doctors went to Florida. Those are not particularly palatable things for Congress to consider, but I don't want to reinforce myths that some of them are currently living under.

DR. ROWE: As I recall our prior conversations with respect to this, in addition to all the factors that you mentioned, Kevin, there have been the problem that over the last three years there have been two years in which there, in retrospect, appear to have been overpayments driven by the SGR, and that induced what has been called by some a correction this year, which I think it was minus 5.4 percent or something along those lines. I think we have actually heard here that it might be somewhat less than that, but it came out about a month after our meeting and it was in that range.

I think when you write up the history and the approaches and the problems with this it would be helpful to have something in a non-judgmental way about these recent changes. Because you can read all this stuff and it's not mentioned at all, and it's kind of a pure analysis of the factors. But the fact is that it hasn't worked. It's not good to overpay, it's not good to underpay, it's not good to have to catch up in one year or in a large way.

The other thing that appears not to have worked is the collars or the corridors in the formula itself. As I recall there is a formula but it's quite wide. It's like minus 7 percent or something that the cutoff is at, so that's a pretty big cut before you have a damping effect on this change. To whatever extent that's accurate you might want to also include something about that as well.

DR. LOOP: Kevin, in that paragraph on controlling spending you mentioned the overuse and misuse. I think in the quality management chapter that preceded you there was mention by PROs citing that underuse was just as bad a problem if not a bigger one. I don't have that chapter in front of me, but you might check and add a line to that. That it's not only overuse and misuse, but underuse has to be addressed.

DR. STOWERS: I was going to talk about what Jack said so I won't expand on it, but I do think we really need to make a bigger point about how broke the current system is. The other thing I have a problem with, and I know Alan has kind of alluded to this, but this is this emphasis on fraud and abuse in this one specific category of health care delivery when we're not trying to control nursing home costs or home health costs or hospital

costs, and we know -- sort of particularly focus in on this in one particular area I think sends a --

DR. NEWHOUSE: Ray, we had huge efforts in home health fraud and abuse.

DR. STOWERS: No, I'm saying we do, and it is important in all sectors including physician services. But to do a huge thing in a particular chapter as the major way of controlling costs in a particular segment I think is well-overemphasized where we are. I think instead of getting contrary to our regulatory burden chapter we could maybe take this from a more positive approach from our quality of care efforts that he's talking about, and quality improvement and so forth, and then let the chips fall where they may.

I just think this chapter could take a lot more positive approach to controlling physician costs than sending the message that we are about fraud and abuse.

DR. REISCHAUER: I thought the other strategies part of this was weak in the sense that these really aren't ways in which, over the long run, we can control spending in Medicare. I'd be in favor of us coming out and forthrightly saying that it is impossible to control spending in Medicare unless you're going to control it systemwide; one. And there's no way to do this without either underpaying, according to our mechanism, providers, or increasing the burden on beneficiaries. We shouldn't pussyfoot around this topic.

DR. HAYES: That's something that's pretty straightforward. That's a pretty blunt statement.

[Laughter.]

MR. HACKBARTH: It's one of his characteristics.

DR. HAYES: We'll work with that.

DR. REISCHAUER: I'm open to somebody saying I'm wrong in saying, have you thought of, but have you thought of isn't coding edits.

DR. ROSS: But, Bob, that was the opening slide on this, right? There are two goals. They're incompatible.

MR. HACKBARTH: But I, for one, like the direct way of saying that. It has more power the way Bob said it than it had on the first slide. I think the powerful statement is a useful one.

MR. MULLER: Just to build on Bob's point, and it's a theme we've been discussing for months, and obviously this commission for years. The efforts, when one looks at efforts to control price and efforts to control quantity, two simple things you multiply to figure out what you're spending, we seem to not be willing to take on the quantity issue very directly in the political process because it's so politically difficult to do so. So we do things, as Alan and Ray objected to, by saying, let's see how much there is in fraud and abuse and keep finessing those kind of issues.

But the broader theme -- and I'm not saying that the politics is going to change in any kind of powerful way, but the broader theme of how one gets the right quantity of services inside the program is an issue that I think has to be faced directly, and different efforts can and should be made to see

what is an acceptable way of dealing with those issues rather than trying to put them underground and thinking that it will somehow happen magically, whether through arbitrary reductions in payments or efforts of fraud and abuse control that may not have that kind of effect.

So I think stating the question here more -- and saying, there's a price issue. As you said, it's compatible with trying to put this all -- have a price and quantity control issue in the same. It's not to say that what I call the quantity issue, the use of services inside the Medicare program should be ignored by us, but they should not be submerged into other kinds of mechanisms and have it be thought that somehow it solves the problem.

You then also get the kind of very perverse effects like an SGR of minus 5.4 which comes out of nowhere, for most people who were expecting it, and it causes the system to -- people to think that the system is wrong, as opposed to it becoming a kind of net result of having incompatible objectives inside there. So I would say, I think Bob expressed it very well, and that we should then at some point think about what kind of appropriate efforts there can be on looking at the quantity of services inside the Medicare program.

MR. HACKBARTH: I'm going to get back to Bob's statement for just a second. I've talked to some people in Congress who, like Bob, think that the cost control mechanisms outlined in the overheads aren't adequate. They're very concerned about the budget implications of the policy changes that we've talked about in the last segment and this one, when you add them up, the dropping of the productivity, even when you factor productivity in later in the analysis it's unlikely to be 1.5 percent, the figure that we've used in the past. We're talking about potentially a huge, a recommendation with huge financial implications for the program here.

So they're very much worried about controlling spending. This stuff won't work. So I know I've been asked, is there any way that the SGR can be fixed; for example, to reduce the volatility? Presumably you could come up with some way to do that. I think it's very important that we stress Bob's point that the other fundamental flaw, or another fundamental flaw of this is that it applies to only one sector of the program. That is a real problem over the longer run.

So if you want to really control spending, I think you've got to look not just at the physician piece but at a broader system of control.

DR. NEWHOUSE: Although I agree with Bob, I'm concerned about coming off with a tone that controlling spending is the preeminent goal. I think there's a lot of evidence that spending could in principle be cut back at any point in time without any real give-up on the benefit side. I think, however, the evidence that the spending increase over time has been driven by things that on balance we want to buy is compelling to me. Kind of in the speaking truth to power of Bob's remarks, I think the general stance ought to be that the expectation will be that in fact this program will continue to grow over time as new innovations come

on stream that on balance cost money but whose benefits are greater than their cost.

DR. REISCHAUER: I agree with that. But I think what we're really questioning is whether the Congress was wise when it decided that physician services should grow at per capita GDP.

DR. NEWHOUSE: We've said no. All the way back to PPRC we've said no.

MR. HACKBARTH: Others?

Okay, thank you, Kevin.

Next is ESRD. Nancy?

MS. RAY: I am here to discuss updating payments for dialysis services for 2003. We are going to follow the same framework that you have seen several times now at this meeting. The first component of the update assesses whether payment rates are too high or too low. The second part of the update assesses how much efficient providers' costs will change in the next payment year. The update recommendation that you will be making in January represents the sum of these two components.

The reason that we are dwelling so much on our update and our update framework, the reason that we care so much about it is that we want to ensure that beneficiaries continue to gain access to high quality care.

Now this is not the first time the Commission has considered updating payments for outpatient dialysis services. ProPAC was initially assigned this task back in the early '90s. For today's presentation I will be presenting evidence about adequacy of payments. Second, I will review changes in dialysis policies since 1999. And lastly, we will look at estimated cost changes for providers in the next payment year.

Medicare is the primary payer of dialysis services. About 91 percent of all patients are Medicare entitled. In 2000, there were roughly about 250,000 dialysis patients. Let me just point out that Medicare is the secondary payer for beneficiaries with employer group health coverage during the first 30 months of dialysis treatment.

Now the three main services that dialysis providers provide to ESRD patients are dialysis. Medicare pays facilities a prospective payment, the composite rate, for the bundle of services which include nursing care, supplies, and certain drugs and lab tests.

Second, providers receive payments for providing certain drugs that are not included in the payment bundle. This includes erythropoietin, and payment for erythropoietin is set by statute. Providers also provide other drugs other than erythropoietin like intravenous iron and vitamin D and injectable antibiotics. For those drugs they get paid 95 percent of AWP.

Third, dialysis patients do receive some laboratory tests that are paid outside of the payment bundle.

Now for composite rate services, erythropoietin and other separately billable drugs, roughly the proportion of payments that providers receive for these services is roughly 65 percent, according to my calculations, 65 percent for outpatient dialysis services, about 27 percent for erythropoietin, and 7 percent for other separately billable drugs.

Now we have not included separately labs in this analysis. That would required a detailed claims analysis and we just have not done that yet. However, from the SEC filing of one of the national dialysis chains, at least for this one very large national chain we do know that lab services represent about 4 percent of dialysis revenues per treatment. So it is smaller than the separately billable drugs.

So the first question that we looked at is looking at payment to cost ratios for services furnished by freestanding dialysis facilities. We've provided you data from 1997 to 2000. There's a couple of points I'd like to make about this graph. Payment to cost ratio for composite rate services continues to decline. It went from 0.98 in 1999 to 0.96 in 2000.

By contrast, payments for separately billable drugs and composite rate services exceeded providers' costs by about seven percentage points in 1997 and 1999. This is the second year now we have tried to compare payments and costs for both composite rate services and separately billable drugs.

Now you'll notice that this graph is missing the data point for 2000 for separately billable drugs. We have encountered a little bit of a problem in getting the separately billable drug data, other than erythropoietin, from CMS, but we're still trying to work on that.

Now with respect to payments and costs for erythropoietin, that actually, we can derive that from the cost report. We at MedPAC had noticed actually an issue with that cost report data. CMS had to go back and give us another file. They have given us additional information this week so you will have that information for the January meeting.

A couple of other points I want to make about this graph. The costs included in this graph represent allowable costs. Providers contend that certain of their costs are not allowable, and that these costs when considered in aggregate are substantial. So let me just go a little bit, let me at least give you what I know about this issue.

Dialysis facilities are required to have a medical director, and the medical director fees Medicare limits according to reasonable compensation equivalent. This was last updated by CMS in May of 1997. So as it stands now, Medicare limits dialysis facilities, the allowable cost, they can claim up to 25 percent of a salary for a medical director and that salary is set at $143,400. Providers contend that that salary is too low.

For example, this comes out to be, if you divide it by 2,080 hours this comes out to be about $69 an hour. They contend that that's too low, and that instead it should be upwards to about $250 an hour. Now facilities can claim additional -- they can raise the proportion of that 25 percent if they provide written justification to CMS.

Another issue that providers contend is that they are not able to get paid bad debt for coinsurance and deductibles associated with separately billable drugs. Now the use of separately billable drugs has increased steadily throughout the 1990s, so it now represents, as we've already talked about, a substantial amount of revenues for dialysis facilities.

Now on the other hand I also want to point out, however, while providers cannot claim bad debt for separately billable drugs, they are paid 100 percent of their allowable ESRD bad debt for composite rate services up to their Medicare reasonable cost. By comparison, other facility providers cannot claim up to the full 100 percent. For example, it's my understanding that hospitals can only claim up to 70 percent.

So I think that we need to consider all of the allowable and non-allowable debts when looking at this graph and the impact that they may make on the lines.

MR. HACKBARTH: Nancy, before you leave that, cumulatively what would be the impact of their argument, in that they say, these costs should be included. Therefore, our margins go from what to what?

MS. RAY: I don't have the margin data. What I do have is that their analysis -- and again, this is their numbers, not my numbers. But allowable costs per treatment would increase from about -- right now allowable cost per treatment is about at $8. If you included unrecognized costs like TV, transportation, and so forth, that would raise it to about $11 per treatment. So a $4 difference.

If you then were to include the non-deductible medical director fees, that would raise it from $11 to $17. So an additional $6 per treatment. Again, that's according to their assumption of paying $250 per hour and then being able to -- up to 25 percent. Now that's their numbers. That's their analysis.

Another caveat about these data. These represent unaudited data. Now you've heard this before from us, that these data are unaudited. But it seemed like throughout the '90s that the data was getting better and better. We make that caveat every year.

This year, there may be a little bit of a difference this year. Congress required CMS to audit 100 percent of dialysis facilities' cost reports. CMS started with the 1996 cost reports. Now 1996 is not on this graph. However, when looking at the new file we are investigating the effect of the audit for the most recent 1996 data. Our preliminary analysis suggests that a greater proportion of facilities have been audited in this 1996 data file. So we are contacting CMS to get clarification about this and we will report to you back about this issue in January.

These findings I don't think necessarily suggest that the cost base for dialysis services is too high. Some contend that Medicare overpaid for dialysis for much of the '80s and early into the '90s. Providers' costs for composite rate services seemed to have caught up with Medicare's payment rate, primarily because Congress did not update the composite rate between 1991 and 2000.

Lastly, both OIG and the GAO have reported that payments for separately billable drugs and drugs paid according to 95 percent AWP substantially exceed providers' cost. Our data suggests that the positive payment margin for the separately billable drugs is helping at least some facilities to subsidize services included in the composite rate.

We looked at a number of market factors to look at adequacy

of payment. The first one is trends in per-unit cost. Providers' cost for composite rate services grew at about the same rate as that predicted by the Commission's dialysis market basket over the 1997 to 2000 time period. Again, this is all according to cost report data allowable cost. Providers' cost increased by about 2.2 percent on average in this time period. By comparison, the market basket increased by about 2.1 percent.

Second, at the same time two important changes have occurred in the dialysis product. The use of injectable drugs such as erythropoietin, iron, vitamin D, and antibiotics during dialysis has increased dramatically throughout the 1990s. For example, total allowed charge for erythropoietin increased from $255 million in 1990 to well over $1 billion in the year 2000. MedPAC's analysis of 1997 to 1999 claims for other injectable drugs other than erythropoietin submitted just by freestanding facilities also shows significant growth in payments for these services from $281 million in 1997 to $489 million in 1999.

I do want to point out though that these separately billable drugs though have contributed to enhancing beneficiaries' quality of care.

The other change I'd like to point out is that the use of in-center hemodialysis has increased throughout the '90s at the expense of home peritoneal dialysis. This trend has occurred even though per-unit costs for peritoneal dialysis is roughly 10 percent lower than the costs for in-center hemodialysis.

We looked at provider entry and exit. We found that the number of dialysis facilities in the U.S. continues to grow, keeping pace with the growth in the number of dialysis patients. The number of facilities grew by about 7 percent on average annually between 1993 and 2000. This growth occurred in rural areas. They increased slightly, the number of facilities growing from about 23 percent to 26 percent in 2000.

One trend that's very clear is that freestanding and for-profit facilities grew at the expense of hospital-based and not-for-profit facilities. Freestanding facilities increased to 82 percent from 70 percent, while for-profit facilities increased to 78 percent from 61 percent during this time period. Dialysis chains continue to consolidate. They are acquiring independent facilities, and they are also partnering with other third party payers and managed care organizations, often to provide disease management for these organizations.

Now some providers are contending that when dialysis facilities close, the facilities that are closing tend to treat a greater proportion of Medicare and Medicaid patients. This is something that in January we will try to look at. We'll try to look at when facilities do close, the characteristics of those facilities, and hopefully we will report back to you in January.

In terms of changes in the volume of services, dialysis treatments grew steadily in this same time period between 1993 and 2000.

In terms of access to high quality care, a review of the published literature shows no hard evidence that beneficiaries are facing problems in obtaining needed dialysis care. Reports of facility closings tend to be spot problems occurring in a few

areas, and they don't appear to be linked to Medicare's policies generally. They tend to be linked to local issues, such as rising real estate prices in certain areas like San Francisco, shortages of technicians and nurses to staff facilities, and state certificate of need regulations.

Quality of care as measured by the clinical performance indicators collected by CMS show continued improvements in the quality of dialysis care as measured by the percent of hemodialysis patients receiving adequate dialysis and those suffering from anemia.

We took a brief look at access to capital. About 80 percent of all dialysis facilities are for-profit, so we looked at their stock price. For-profit stocks of dialysis providers have in large part enjoyed positive investment rates by financial analysts over the last year.

Taken together, on balance nothing suggests that total payments to dialysis facilities are not inadequate although Medicare's payments for composite rate services did not appear to be covering providers' costs in 2000.

Now changes in outpatient policies since 1999. Congress updated the composite rate by 1.2 percent in 2000, and 2.4 percent in 2001. Current law does not include any update for 2002 or 2003.

The other item on the horizon is that BIPA required CMS to submit a report to the Congress on revising the payment bundle by broadening the payment bundle and updating payments for dialysis services. This report is due to the Congress in July of 2002.

Staff did not find any evidence that should suggest that providers' costs are expected to change significantly due to new medical advances, one-time factors, or productivity improvements in the next payment year. I think it's probably appropriate to assume that costs of new medical advances will be offset by productivity improvements, as you were doing for several other services areas.

Now CMS has not developed a market basket yet for outpatient dialysis services. They're working on that right now. ProPAC developed a market basket that uses information from price indices for PPS hospitals, SNFs, and home health agencies. This market basket again predicts that providers' costs will increase by 2.6 percent between 2002 and 2003.

Now the other issue I would like to point out that may affect providers' costs in the next payment year is that the manufacturer for erythropoietin announced a price increase of 3.9 percent. This increase was announced in 2001. I do want to point out though that this price increase does not impact providers equally because each provider negotiates the price of erythropoietin with the manufacturer.

So to summarize, total payments do not appear to be inadequate. Payment to cost ratios for both composite rate services and separately billable drugs was on average seven percentage points -- was 1.07 in 1999. Evidence about other market conditions show no indications that payments are not inadequate.

We would like for you to begin your discussion about whether

any adjustment is needed to bring the current payment rates to the most appropriate level, and whether adjustment is needed to account for efficient providers' cost increases in the next payment year.

DR. LOOP: Let me make one attempt to simplify some of this. Erythropoietin, or EPO, is used in 90 percent of the patients, and there's a new EPO that's coming onto the market that's a long duration EPO.

MS. RAY: Yes. It's come to my attention, however, that that's going to be primary marketed -- the information that certain providers have told me is that the longer acting agent is primarily going to be marketed to pre-ESRD patients and non-ESRD patients, not ESRD patients.

DR. LOOP: But it will catch up real quick, I would think. Anyway, let me go on now.

If there is a better EPO, why not fold that into the base rate?

MS. RAY: The Commission has recommended to the Secretary that we broaden the bundle, and HCFA is working on that study right now. I think it would certainly -- I would think that a longer acting EPO that only has to be given once a week would certainly enhance quality of care, particularly for those patients who are not compliant about coming in three times a week, yes.

DR. LOOP: Right. If it was put into the composite rate that would seem to get rid of the EPO issue for a while. And if there is an outpatient market basket, which is apparently being developed, I would think because of the increase in technology in this area that it should be updated every year. That would be an index that shouldn't wait five years.

Alan probably should comment on some of this, and Jack if he's been recertified.

[Laughter.]

DR. ROWE: I have a response to that cheap shot. I was board certified so long ago I am grandfathered and don't have to be recertified, to give an idea of how old I am. I have a couple questions.

MR. HACKBARTH: I have Bob, then Jack, Sheila.

DR. REISCHAUER: I actually have a clinical question for Jack and Floyd and Alan. Listening to the presentation, Nancy, and not really knowing anything about this and bringing my tools as an economist to it, I hear you saying the composite rate is inadequate but to sustain profitability they make it up on drugs, on EPO and other things. So the first reaction that I would have is, clinically, is this providing an incentive for them to use too much in the way of drugs. Floyd says 95 percent of the people use EPO, but is there a question of how much you use?

DR. ROWE: This question has been adjudicated. My understanding is that one of the largest firms, if not the largest firm, was sued by Medicare and there was a settlement in the range of $500 million with respect to questions regarding the overuse of certain medications like EPO and certain nutritional supplements.

So that issue has been resolved, at least in a looking

backward way, and my assumption would be that the monitoring is such that to whatever extent there may have been some overtreatment in the past -- and I'm not saying there was, but there was as settlement. To whatever extent there may have been overtreatment in the past, my expectation is that it is carefully monitored.

We have, in our company, many dialysis patients as well and we're mindful of these incentives and carefully monitor the utilization of these various adjunctive treatments. So I think that that issue is well recognized, Bob.

DR. REISCHAUER: What you said wouldn't make me sleep easy. What it would say is, this egregious overuse is no longer available, but around the edge the incentive still is there. But then if we go to the bundling issue the incentive turns out to be just the opposite, which would be to stint on these. And where you want to draw the line and how much regulation you want to do I think is a difficult kind of issue.

But at a minimum we should want the composite rate to reflect the costs, and what this suggests is that, and Nancy said as much, that 95 percent of the AWP is overpaying for these drugs and we're underpaying for the composite rate. Rebalancing that at least will reduce some of the incentives. But I have --

DR. ROWE: That's right. But let me respond also to this once more if I may. I think that to whatever extent Floyd's prediction turns out to be true, that there are competitive agents coming on the market with respect to EPO, that's going to reduce expenditures. I know you don't think there are but --

MS. RAY: It's the same manufacturer.

DR. ROWE: But there is another manufacturer in Europe that has released, I think this week, an agent that I think will be licensed worldwide by Glaxco that is a competitor. So I believe it is possible that there will be additional agents. If that happens there will be compression of the margins with respect to EPO, which is what they're living on now, and we'll be left with the inadequate base rate. So it really that much more emphasizes the value of the strategy that you're --

DR. REISCHAUER: But I mean, not necessarily. If we're paying -- EPO we have a flat amount, but these other drugs you're paying 95 percent of the AWP. So from the standpoint of both the manufacturer and the dialysis firm, having the highest AWP possible is the way to maximize everybody's happiness.

I have a supplementary question before you say I'm all wrong on that, Nancy.

MS. RAY: I just want to point out two things. Medicare's payment policy for erythropoietin does provide limits, does limit -- actually it's done by the patient's hematocrit. Providers cannot provide erythropoietin if the patient's hematocrit goes over a certain level. So Medicare does have at least some sort of limit that way.

What we did point out, not in your mailing papers but last year's report, we did point out that this separately billable drugs are not as efficiently provided as they might be. For example, erythropoietin can be provided either IV or subcutaneously. Subcutaneously, on average, is a lower dose, yet

you find most patients receive the drug IV. Some of the other separately billable drugs there are oral formulations. Again, because Medicare doesn't pay for those oral formulations they're given to the in-center patients intravenously.

So I do agree with you that broadening the bundle could help address these issues.

DR. REISCHAUER: Let me go to the second, where I am board certified to talk. You talk about the number of facilities. I'm wondering how useful that is. Don't we really care about capacity? It's sort of like counting the number of food stores when some are ma-and-pa stores and some are Giants. I don't know how this industry operates, but I'd be more concerned about the growth and the shrinkage of capacity than the actual number of facilities.

You mentioned that you were going to do some analysis of the composition of the beneficiaries in facilities that have closed to see if they were skewed in one way or another. But I thought I read somewhere that like over 90 percent were Medicare eligible anyway, so how skewed can you get?

MS. RAY: The data that providers have shown me -- and again, this was limited to just two dialysis chains. There was a relative small number of closures did show a slightly higher percentage of patients, among the facilities that closed, a slightly higher percentage of patients were Medicare or Medicaid.

Now I think the one issue is, again, they did their analysis by treatments because they have their data broken down by treatments. I think that's important because it goes back to the MSP issue, whether or not Medicare is the primary payer or the secondary payer. Now I don't have that type of data. All I have is whether -- I don't have the MSP information. So the MSP issue and the fact that MSP is for the first 30 months for patients who have employer group health coverage could affect these data.

MS. BURKE: The question that I had is, in the context of determining a composite rate that is in fact adequate, in addition to EPO, in addition to the other drugs which are largely the iron and vitamin D and antibiotics as I recall, is there anything else missing from the composite rate that we believe needs to be taken into consideration if we in fact are going to adjust that base? That's my first question. Other than drugs, is there a key component missing from the composite rate outside?

MS. RAY: Laboratory tests. But again, we don't have the data; I don't have the data for that yet.

MS. BURKE: So if we were to suggest as policy that we believe more things ought to be bundled, to remove the incentive which varies. In some cases, as you suggest with the case of EPO there's a fairly clear clinical direction that has to be taken. In the other cases it's a little more fluid. Do we in fact have sufficient data to base a rate on an appropriate mix? If we're going to suggest moving towards a broader composite rate, do we believe in fact that we have sufficient information to know what that rate ought to be based on in terms of the averages of cost of this mix of services?

MS. RAY: CMS right now is studying that issue and I think we would probably be better off waiting for CMS to look at CMS's

study on how they are envisioning to broaden the payment bundle.

MS. BURKE: And the timing of that is what?

MS. RAY: It's due to the Congress July of 2002.

MS. BURKE: The CMS study is due?

MS. RAY: The CMS study, right. Congress required CMS to study --

MS. BURKE: To report, right.

MS. RAY: Not to implement, just to study and give them a report about it.

MS. BURKE: So as we look forward to what it is that we might suggest, what will we be in position to comment on in January, given that? That we think that we ought to move to a broader composite rate but we're not sure what it ought to include? I'm trying to understand the framework in which we are making a decision, knowing full well we in fact don't know yet what that rate ought to be based on because we don't have the data.

MS. RAY: Right. Now last year the Commission did recommend broadening the composite rate bundle. For this year we are asking, for January we are asking you to make an update recommendation for composite rate services only.

MS. BURKE: Absent any of these further longer term adjustments. Just simply the market basket based issues, not whether it's a broader bundle.

MS. RAY: Right.

DR. ROWE: A couple comments. One clinical point. Nancy, first of all, I appreciate, I'm sure we all appreciate your sustained hard work in this area and your increasing body of knowledge about it. Just on the issue of the EPO administration. It is true that if you give it subcutaneously you get a lower dose. Except there are two problems with that. One is it hurts. While the patient is on the dialysis machine you can give it intravenously and there's no discomfort.

The second is, of course, when the patient is being dialyzed they're anticoagulated. So if you give them a subcu injection you run the risk of them having a hemorrhage or a hematoma. So you would have to give a subcu injection at another time when they're not anticoagulated, which would mean they'd have to come in from home to get the subcu injection of the EPO.

MS. BURKE: Actually, Jack, didn't we do self-administration at some point in the '80s?

MS. RAY: Medicare does pay for EPO whether it's administered in-center, at home, whether it is self-administered.

DR. ROWE: So anyway, there are clinical issues here.

Secondly, I think that when we were talking about hospitals, adequacy of hospital payment rates yesterday we used their share price, their corporate valuations, the creditworthiness, et cetera, of the for-profit hospitals as a measure of their adequacy of payment. So I would think just to be consistent we might -- you mentioned that when you talked about access to capital. But in terms of the analysis of the adequacy of payment you might consider that same analysis to just make it parallel with yesterday's.

Thirdly, there has been a relatively low inflation in the

cost, and in fact one year I saw it was 1.8 percent increase in the input costs. I'm assuming that the relatively low inflation rate in these costs is related to increasing reuse of dialyzers, but that's not mentioned. It would be interesting to know whether that in fact is the case.

MS. RAY: We presented some numbers on reuse in last year's report, and I will go ahead and update them and present them to you for January. But the trend has been for increasing reuse. I do want to say though that at least from information providers give me, that there may actually be a change in that trend toward single-use dialyzers in the future.

DR. ROWE: I think that's true, but I don't think that's happened yet.

Next to last, you showed data with respect to anemia, urea reduction rates and hyperalbumanemia. They're all going in the right direction and it looks like quality is increasing quite dramatically, up until '98 at least which is the last data you show. We had been concerned a couple of years ago that what we were seeing compared to Europe was higher mortality rates and that we were seeing a frequent, shorter dialyses in the United States. There was this issue of you get paid per dialysis but you're getting a shorter dialysis experience, so the total number of hours of dialysis is less, et cetera.

So I wondered whether there had been any change in the duration of dialysis and in the mortality rates, and how we're doing compared to Europe, if you know.

MS. RAY: First of all, comparing mortality to Europe has to be done, I think, very carefully just because of the differences in case mix and who gets treated and so forth. So I guess I'd like to -- there have been studies doing that. There is actually a large study now being done on that. To be honest with you, I am not current with the findings of that study, but I will be and present you that data in January.

With respect to the length of dialysis, recent trends do not suggest that session length is decreasing. But again, I will go and get those data, the most current data and give those to you in January.

DR. ROWE: So it's frequency, session length, total number of hours of dialysis over time. We want to make sure we're not churning the system here with paying per session for frequent, shorter sessions.

The last point is that I note the migration of dialysis units away from hospitals and not-for-profit status into freestanding and for-profit status. I think that that's not necessarily a bad thing in any way at all. What this is all about is delivering high quality care. I think that it relates to some of the discussion we had yesterday about hospitals not having, not-for-profit hospitals at least not having access to capital. This is a relatively capital-intensive type of unit to establish on the one hand.

Secondly, I think it relates to the economies of scale that the large corporations have, and their purchasing power and what have you, with respect to EPO and dialyzers, et cetera. So I think that probably does explain this.

There's also a fair amount of regulation that you might look into, which is I think highly variable. There are still states that have basically certificate of need type of programs to apply dialysis stations, and there are other states that do not. That might be an interesting thing for you to look at with respect to entry, et cetera.

Thank you, Nancy.

MR. HACKBARTH: We're down to our last couple minutes here. Did you have a comment, Floyd, directly on this?

DR. LOOP: Nancy, I wanted to also if you can include three things because they do have some longer term implications. One is a progress and quality assessment, because I think that's getting better as it goes on.

The second is some information about frequency of treatment, which Jack mentioned, because there is a -- the number of dialysis episodes per patient, I believe, is beginning to increase. They're going towards multiple sessions a week rather than just once a week.

The third is, as more populations are being dialyzed, if you could find out what the impact is on dialysis of nursing home patients, because I think that's increasing. I think it was Bob that mentioned something about capacity versus demand. As you know, if there's a niche, somebody is going to fill it. So that's part of the culture of American health care. It's not anything against the for-profit dialyzers.

MS. BURKE: You mentioned or you referenced the increase again in reuse, that we're going back to the old days of reuse; at least I remember them as the bad old days. I don't know whether or not that is something on which we ought to comment at some point, whether that is something that people feel better about, whether in fact that is contributing to reductions in cost, technologies increase. But at least historically that was something that we viewed with a fair amount of suspicion and had a series of real issues, at least in the '80s.

MS. RAY: I will take on the reuse issue for January.

DR. NELSON: Nancy, are the oral alternatives that you mentioned to parenteral medications a covered benefit?

MS. RAY: No.

DR. NELSON: So one of the reasons for the recipients getting those at the time of dialysis would be that they'd have difficulty affording those as an alternative, outpatient? I guess the point that I want to make is that if indeed we want to encourage alternatives to parenteral use, we ought to comment in some fashion about the composite rate including some coverage for that, for those oral alternatives.

MS. RAY: I agree with you with that, yes. Again, that goes back to our recommendation that we made last year about broadening the payment bundle.

DR. NEWHOUSE: Given that we only have to recommend what we're going to do on the composite rate what I'm about to say may be moot. But to the degree we get into a discussion of EPO and EPO margins in this report I'd want to make sure that we try to maintain consistency with the chapter we're about to talk about next, which is going to talk about shifting things away from AWP

toward transaction prices or fee schedules or what have you, but in any way off AWP. I think we want to try to treat EPO similarly as we're going to treat outpatient technology.

MR. HACKBARTH: Thanks, Nancy. We'll see you in January. You'll come with a big notebook.